

Remarks

Requirement for Restriction

The Restriction Requirement divides the claims into two groups:

- I. Claims 1-3, 6, 7, 9-14, 23-26, and 29-31, directed to a method of managing treating or ameliorating a respiratory infection comprising administering an effective amount of an IL-9 antagonist in a human subject suffering from the respiratory infection; and
- II. Claims 4-8, 15-23, 27-28, and 32-36, directed to a method of managing, treating or ameliorating a respiratory infection comprising administering an effective amount of an IL-9 antagonist and an effective amount of at least one other therapy that is not administration of an IL-9 antagonist in a human subject suffering from the respiratory infection.

See Restriction Requirement at page 2 lines 4-13. As an initial matter, Applicants wish to clarify the subject matter encompassed by the claims in Groups I and II.

The independent claims of Group I, claims 1, 2, and 3, are not solely directed to a method of managing, treating, or ameliorating a respiratory infection. Claim 1 is directed to a method of managing, treating, or ameliorating a respiratory infection, or a symptom thereof. Claim 2 is directed to a method of preventing onset or progression of one or more asthma-like symptoms or asthma in a human child that previously had a respiratory infection or concurrently has a respiratory infection. Claim 3 is directed to a method of preventing, managing, treating, or ameliorating wheezing in a human preterm infant a human infant or a human child. These methods comprise a step of administering an effective amount of an IL-9 antagonist.

The subject matter of the independent claims of Group II, claims 4 and 5, is apparently improperly characterized by the examiner. Claim 4 recites “[a] method of preventing, managing, treating or ameliorating wheezing in a human subject suffering therefrom.” Claim 5 recites “[a] method of preventing, managing, treating or ameliorating asthma or an allergy, or one or more symptoms thereof.” These methods comprise

administering an effective amount of an IL-9 antagonist and an effective amount of at least one other therapy.

Applicants respectfully traverse the restriction of the claims into these two groups.

The Manual of Patent Examining Procedure (M.P.E.P) § 803 (I) sets forth two criteria for restriction between patentably distinct inventions which include:

- (A) The inventions must be independent or distinct; *and*
- (B) There would be a serious burden on the examiner if restriction is not required.

Emphasis added.

Applicants respectfully submit that the subject matter of Groups I and II should not be restricted because any search of these two groups would be co-extensive and therefore not impose a serious burden on the Patent Office.

The claims of Groups I and II, as restricted by the Patent Office, all comprise a step of “administering ... an effective amount of an IL-9 antagonist.” The Restriction Requirement points out a single distinguishing feature between the Group I and II claims: the methods claimed in Group II additionally comprise administering an effective amount of at least one other therapy. See Restriction Requirement at the sentence bridging pages 2 and 3. Any search for methods which comprise (i) *administering an IL-9 antagonist* and (ii) at least one other therapy (Group II) will *necessarily* produce search results relevant to methods which comprise (i) *administering an IL-9 antagonist* (Group I) and vice versa. Because a search of either of the Group I or II claims will necessarily produce results for the other, a search of the claims in these two groups is co-extensive. Such a co-extensive search will not impose a serious burden on the Patent Office.

Furthermore, the claims designated as being in Groups I and II have not acquired a separate status in the art. The claims in both Groups I and II are classified in class 514,

subclass 1. This identical classification supports Applicant's position that co-examination of these Groups would not impose a serious burden on the Patent Office.

Election

To fully comply with the Restriction Requirement, Applicant elects the claims designated in Group I (claims 1-3, 6, 7, 9-14, 23-26, and 29-31). To further comply with the Restriction Requirement, Applicant elects influenza virus as the species for examination. Claims 1-3, 6, 7, 9, 10, 12, 13, 23-26, 29, and 30 read on the elected species.

Should the Patent Office deem the Restriction Requirement proper and proceed with examination of Group I, it should reconsider the designation of Group II claims 8, 15-19, and 22. While claims 8, 15-19, and 22 are designated in Group II, they *solely* from Group I claims, *i.e.*, *none* of these claims (8, 15-19, and 22) depend from a single Group II claim. Clearly, a search of the Group I claims from which claims 8, 15-19, and 22 depend will be relevant to and co-extensive with any search of claims 8, 15-19, and 22. Thus, inclusion of claims 8, 15-19, and 22 in Group I will not impose an undue burden on the Patent Office.

Similarly, the Patent Office should re-designate Group II claims 32-36 as being in both Groups I and Group II. Claims 32-36 ultimately depend from both Group I and II claims. A search of the Group I claims from which claims 32-36 depend will be relevant to and co-extensive with a search of claims 32-36 (to the extent that they depend from the Group I claims). Applicant therefore believes that re-designating Group II claims 32-36 in both Groups I and II will not impose an undue burden on the Patent Office.

Respectfully submitted,

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